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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,398	08/23/2006	Petra Gisela Rigassi-Dietrich	33688-US-PCT	8737

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 101/2
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EXAMINER	
VU, JAKE MINH	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,398	RIGASSI-DIETRICH ET AL.	
	Examiner	Art Unit	
	JAKE VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *15-23 and 26-52* is/are pending in the application.

5a) Of the above claim(s) *15-20,23,30 and 31* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *21,22,26-29 and 32-52* is/are rejected.

8)☒ Claim(s) *33 and 35-38* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/17/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 11/17/2011; and Information Disclosure Statement filed on 08/17/2011.

- Claims 21-22, 28-29, 32-33, 35-38 have been amended.
- Claims 40-52 have been added.
- Claims 24-25 have been cancelled.
- Claims 15-23, 26-52 are pending in the instant application.
- Claims 15-20, 23, 30-31 are withdrawn from consideration.

Claim Objections

Claims 33, 35-38 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 33, 35-38 recites an oral dosage form according to claim 21, further comprising fillers, disintegrant, lubricant, glidant, and binder. However, claim 21 already have fillers, disintegrant, lubricant, glidant, and binder.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-22, 26-29, 32-52 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application No. 11/153,728; 11/119,273; and 11/219,273 **are maintained** for reasons of record in the previous office action filed on 03/09/2009.

Note, it is acknowledged that Applicant requests that the Office hold all provisional double patenting rejections in abeyance pending claim allowance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, pertaining to claim 32 recites the limitation "about 332 mg" in claim 29, **is withdrawn** in view of the amendment to claim 32.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-22, 24-29, 32-39 are rejected under 35 U.S.C. 102(a,e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WEBB (US 2003/0114389) **are withdrawn** in view of Applicant's Amendment.

However, upon further consideration of Applicant's Amendment, a new ground(s) of rejection is made as discussed below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-22, 26-29, 32-42, 44-47, 50-52 are rejected under 35 U.S.C. 102(a,e) as being anticipated by WEBB (US 2003/0114389) as evidence by DRUG FACTSHEETS (http://chealth.canoe.ca/drug_info_details.asp?brand_name_id =4983&rot=4).

Applicant's claims are directed to a composition comprising of: an inner phase containing: a drug, such as aliskiren; filler; binder; disintegrant, and an outer phase containing: disintegrant; filler; glidant; lubricant, and a film coat containing hydroxypropyl methylcellulose; iron oxide pigment; titanium dioxide; polyethylene glycol and talc.

WEBB teaches a composition comprised of: a granule (see [0078]), which reads on an inner phase containing: 100mg (see [0077]) of formula I (see [0001]), which is aliskiren, in the hemi-fumarate salt form (see [0077]); colloidal silicic acid, which reads on a filler, since it would occupy volume space; starch paste, which reads on a binder; corn starch, which reads on a disintegrant (see [0077]-[0078]), and an outer phase containing: sodium carboxymethyl starch, which is a disintegrant; corn starch, which can be a filler, since it would occupy volume space; magnesium stearate, which is a glidant; stearic acid, which is a lubricant (see [0077]-[0078]), and an opadry yellow film coat (see [0076] and [0080]), which contains hydroxypropyl methylcellulose; iron oxide pigment; titanium dioxide; polyethylene glycol and talc. Additional disclosure includes: about 1-80% of the active compound (see [0067]); 45.5% of aliskiren (see example in [0077]); the active compound could be made in ranges of 10-500mg (see [0072]); the composition could be made by other methods than wet granulation, such as convention mixing, coating, and lyophilizing processes (see [0067]); pharmaceutical preparations

are prepared in a manner that is known per se (see [0067]); WEBB also disclosed another drug formulation in Example 2, wherein the inner phase contain: microcrystalline cellulose (see [0079]), which is well-known to be a filler; povidone, which is polyvinylpyrrolidone and can be used as a binder (see [0079]); croscarmellose sodium, which is a well-known disintegrant; and an outer phase containing: a disintegrant, such as croscarmellose sodium; glidant, such as colloidal silicon dioxide; and a lubricant, such as magnesium stearate (see [0079]-[0080]).

Note, with regard to claim 39, this claim recites a composition, and the intended use recited in the preamble would reasonably appear not to be a claim limitation. "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim…If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). Thus, the intended use of treating hypertension in the composition claims is met by the prior art, because the prior art compositions would be at least capable of performing said use.

Note, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, the method of producing the composition by not using wet granulation with excipients using water and/or an aqueous binder solution has no patentable limitation, since the prior art's product has the same ingredients as claimed by Applicant.

DRUG FACTSHEETS disclosed that opadry yellow coating contains polyethylene glycol, hypromellose, which is hydroxypropyl methylcellulose, iron oxide yellow, talc, and titanium dioxide (see pg. 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-22, 26-29, 32-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over by WEBB (US 2003/0114389) as evidence by DRUG FACTSHEETS (http://chealth.canoe.ca/drug_info_details.asp?brand_name_id =4983&rot=4) in view of UPADHYAY et al (US 2001/0044472).

As discussed above, WEBB teaches a composition comprised of: a granule (see [0078]), which reads on an inner phase containing: 100mg (see [0077]) of formula I (see [0001]), which is aliskiren, in the hemi-fumarate salt form (see [0077]); colloidal silicic acid, which reads on a filler, since it would occupy volume space; starch paste, which reads on a binder; corn starch, which reads on a disintegrant (see [0077]-[0078]), and an outer phase containing: sodium carboxymethyl starch, which is a disintegrant; corn starch, which can be a filler, since it would occupy volume space; magnesium stearate, which is a glidant; stearic acid, which is a lubricant (see [0077]-[0078]), and an opadry yellow film coat (see [0076] and [0080]), which contains hydroxypropyl methylcellulose; iron oxide pigment; titanium dioxide; polyethylene glycol and talc. Additional disclosure includes: about 1-80% of the active compound (see [0067]); 45.5% of aliskiren (see example in [0077]); the active compound could be made in ranges of 10-500mg (see [0072]); the composition could be made by other methods than wet granulation, such as convention mixing, coating, and lyophilizing processes (see [0067]); pharmaceutical preparations are prepared in a manner that is known per se (see [0067]); WEBB also disclosed another drug composition in Example 2, wherein the inner phase contain: microcrystalline cellulose (see [0079]), which is well-known to be a filler; povidone, which is polyvinylpyrrolidone and can be used as a binder (see [0079]); croscarmellose sodium, which is a well-known disintegrant; and an outer phase containing: a disintegrant, such as croscarmellose sodium; glidant, such as colloidal silicon dioxide; and a lubricant, such as magnesium stearate (see [0079]-[0080]). Note, with regard to claim 39, this claim recites a composition, and the intended use recited in the preamble

would reasonably appear not to be a claim limitation. "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim…If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). Thus, the intended use of treating hypertension in the composition claims is met by the prior art, because the prior art compositions would be at least capable of performing said use. Note, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, the method of producing the composition by not using wet granulation with excipients using water and/or an aqueous binder solution has no patentable limitation, since the prior art's product has the same ingredients as claimed by Applicant. DRUG FACTSHEETS disclosed that opadry yellow coating contains polyethylene glycol, hypromellose, which

is hydroxypropyl methylcellulose, iron oxide yellow, talc, and titanium dioxide (see pg. 2).

WEBB does not teach that Example 2 use the active drug aliskiren; or using a specific disintegrant, such as crosslinked-polyvinylpyrrolidone; or having a filler in in the outer phase of Example 2.

UPADHYAY teaches that disintegrants are known in the art and include, for example, crosslinked polyvinylpyrrolidone (also known as crosslinked povidone) and crosslinked sodium carboxymethylcellulose ("croscarmellose sodium") (see [0020]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate aliskiren as the drug into Example 2 in the WEBB reference. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because the WEBB reference is not limited by the Examples only, since WEBB teaches using drugs, such as aliskiren and nateglinide, it would have been obvious for one skilled in the art to interchange the active drugs in every Examples.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate crosslinked polyvinylpyrrolidone in place of the croscarmellose sodium in the WEBB reference. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because crosslinked polyvinylpyrrolidone and croscarmellose sodium are functional equivalents commonly used in the art as disintegrants.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate a filler, such as corn starch or microcrystalline cellulose, into the outer phase of Example 2, since Example 1 teaches using corn starch in the outer phase of Example 1. The person of ordinary skill in the art would have been motivated to make those modifications, because it would allow the tablet to be enlarge for easier handling by the patients, and reasonably would have expected success because a filler in the outer phase was used in Example 1.

Response to Arguments

Applicant argues that the "filler" identified by the Examiner is never used or identified as being useful in an aliskiren formulation. Rather, Example 2 of Webb refers to the use of microcrystalline cellulose in a nateglinide formulation.

The Examiner finds this argument unpersuasive, because as discussed above, any ingredient would be considered a filler, since every ingredient occupy volume space. Additionally, as discussed above, the teaching of the WEBB reference is not limited by the examples or else Applicant's claims would be limited by the Specification's examples.

Applicant argues that aliskiren is a difficult drug to formulate, wherein the inventors of the instant invention found that it was important to have the disintegrant excipient in both the inner and outer phase of the tablet in order to have a suitable disintegration time.

The Examiner finds this argument unpersuasive, because as discussed above, WEBB has disintegrant excipients in both the inner and outer phase of the tablet in Example 1 and 2.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618